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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,512	11/14/2003	Todd K. Whitehurst	AB-269U	9960

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EXAMINER	
JOHNSON, SHEVON ELIZABETH	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,512	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Shevon E. Johnson	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/8/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 7 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 12-17 of copending Application No. 10/346,538. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims reference systems comprising a stimulator that generates infusion/electrical pulses, a catheter for delivering drugs, a lead, and an electrode for treating heart disorders.

Claims 1, 2 and 5-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/285,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims reference systems comprising a stimulator that generates infusion/electrical pulses, a catheter for delivering drugs, a lead, and an electrode for treating heart disorders.

Claims 1, 5-7 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-5 and 13 of copending Application No. 10/211,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because

both sets of claims reference systems comprising a stimulator that generates infusion/electrical pulses, a catheter for delivering drugs, a lead, and an electrode for treating heart disorders.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-7, 11, 12 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Struble (U.S. Patent Pub. 2002/0188327), cited by examiner or WO 02/087688, cited by applicant.

In regards to claims 1 and 3, Struble discloses a method for treating congestive heart failure, comprising: providing a first stimulator 118 that generates an infusion pulse in accordance with prescribed parameters; providing a catheter 126, 134 connected to the first stimulator, which catheter includes a discharge portion; providing a second stimulator 102 that generates an electrical (defibrillation) pulse in accordance with prescribed parameters; providing a lead 106, 108 connected to the second stimulator, which lead includes at least one electrode 110, 112, 114; implanting the catheter discharge portion and the at least one electrode near at least one cardiac tissue to be stimulated; implanting the first stimulator and the second stimulator at a location remote from the at least one tissue to be stimulated; tunneling the catheter subcutaneously to the first stimulator location; delivering via the first stimulator and catheter, infusion pulses of at least one drug as at least one treatment for congestive heart failure to the at least one cardiac tissue; and delivering via the second stimulator and lead, at least one electrical stimulating pulse to tissue surrounding the at least one electrode (pgs. 6-8, [0062-0080]; fig. 6).

In regards to claim 2, Struble discloses the method wherein the first stimulator and the second stimulator are one stimulator (pgs. 7 and 8, [0079]).

In regards to claims 4 and 5, Struble discloses the method comprising infusing an antiarrhythmic agent (pg. 7, [0070]).

In regards to claims 6 and 7, Struble discloses the method wherein the at least one drug provides acute treatment on demand or chronic treatment delivered at a basal rate or via periodic bolus with at least one of an antiarrhythmic agent (pg. 7, [0070, 0077, 0082]).

In regards to claim 11, Struble discloses the method comprising providing at least one sensor to sense a physical condition, and adjusting the parameters based on the sensed condition (pgs. 4 and 6, [0039, 0064]).

In regards to claims 12 and 16-18, Struble discloses a method for treating chronic heart failure (CHF), comprising: implanting a fully implantable stimulator system for generating stimulating (defibrillation) pulses; administering via the stimulator system stimulating pulses of at least one acute CHF drug; administering via the stimulator system stimulating pulses of at least one chronic CHF drug; and administering via the stimulator system stimulating pulses of at least one drug that reverses CHF (pgs. 6-8, [0062-0080]; fig. 6).

In regards to claims 14 and 15, Struble discloses the method wherein the at least one drug provides acute treatment on demand or chronic treatment delivered at a basal rate or via periodic bolus with at least one of an antiarrhythmic agent (pg. 7, [0070, 0077, 0082]).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-7, 11, 12, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funke (U.S. Patent No. 4,987,897) in view of Altman (U.S. Patent Pub. No. 2001/0044619) or Goedeke (U.S. Patent No. 5,904,708) or Elsberry et al. (U.S. Patent No. 5,662,689) or Thompson (U.S. Patent No. 6,571,125), as cited by the examiner.

In regards to claims 1 and 11, Funke '897 discloses the method substantially as claimed comprising providing a first stimulator 77 that generates an infusion pulse, second stimulator 10 that generates an electrical pulse, a lead 21 connected to the second stimulator, which lead includes at least one electrode 20; implanting the first stimulator and the second stimulator at a location remote from the at least one tissue to be stimulated; and delivering via the second stimulator and lead, at least one electrical stimulating pulse to tissue surrounding the at least one electrode (col. 8, line 63 – col. 9, line 36; fig. 5). Funke '897 discloses providing at least one sensor 84 to sense a physical condition, and adjusting the parameters based on the sensed condition (col. 9, lines 37-59). Funke '897 fails to disclose a catheter connected to the first stimulator. However, Altman '619 teaches the use of a catheter connected to the first stimulator (pgs. 8-9, [0088, 0090, 0093, 0100-0101]; figs. 3A, 3C, 4). Likewise, Goedeke '708 (fig. 4), Elsberry '689 (fig. 1), and Thompson '125 (fig. 5) also teach a catheter connected to the first stimulator/pump.

One having ordinary skill in the art would appreciate that Funke '897 and either Altman '619, Goedeke '708 (fig. 4), Elsberry '689, or Thompson '125 could be combined since they teach systems and methods for treating cardiovascular disorders, and thus the references are analogous art. Lacking any criticality, to have specified that the first stimulator of Funke '897 includes a catheter would have been obvious to one of ordinary skill in the art at the time of the invention in view of the well-known combination of implanted stimulators and drug delivery catheters, as taught by Altman '619, Goedeke '708 (fig. 4), Elsberry '689, or Thompson '125.

In regards to claim 2, Altman '619 (figs. 6A, 6B), Goedeke '708 (fig. 4), Elsberry '689 (fig. 1) or Thompson '125 (fig. 5) show wherein the first stimulator and the second stimulator are one stimulator.

In regards to claim 3, Altman discloses the method wherein the at least one electrical stimulating pulse is a defibrillation pulse (pgs. 9 and 10, [0104-0108]; figs. 6A and 6B).

In regards to claims 4 and 5, Altman discloses the method comprising infusing an antiarrhythmic agent (pg. 3, [0020-0023]).

In regards to claims 6 and 7, Altman discloses the method wherein the at least one drug provides acute treatment on demand (pg. 4, [0056]) or chronic treatment delivered at a basal rate or via periodic bolus (pg. 8, [0088, 0090]) with at least one of an antiarrhythmic agent (pg. 3, [0020-0023]).

In regards to claims 12, 17 and 18, Altman discloses a method for treating chronic heart failure (CHF), comprising: implanting a fully implantable stimulator system for generating stimulating (defibrillation) pulses; administering via the stimulator system stimulating pulses of at least one acute CHF drug; administering via the stimulator system stimulating pulses of at least one chronic CHF drug; and administering via the stimulator system stimulating pulses of at least one drug that reverses CHF (pg. 4, [0033]; pgs. 9 and 10, [0104-0110]; figs. 6A and 6B).

In regards to claims 14 and 15, Altman discloses the method wherein the at least one drug provides acute treatment on demand (pg. 4, [0056]) or chronic treatment delivered at a basal rate or via periodic bolus (pg. 8, [0088, 0090]) with at least one of an antiarrhythmic agent (pg. 3, [0020-0023]).

In regards to claim 16, Altman discloses the method wherein the stimulating pulses are administered to at least one of a coronary artery, a branch of a coronary artery, a coronary vein, a branch of a coronary vein, the aorta, the left ventricle, the right ventricle, the left atrium, the right atrium, a pulmonary vein, and a pulmonary artery (pg. 4, [0033]).

6. Claims 8-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struble '327 or Funke '897 and Altman '619 in view of Rosenzweig et al. (U.S. Patent Pub. No. 20020040010) or Miyamoto, Michael et al., "Adenoviral Gene Transfer of SERCA2a Improves Left-Ventricular Function in Aortic-Banded Rats in Transition to Heart Failure," PNAS (2000), vol. 97, No. 2, pp. 793-798, as cited by the applicant.

In regards to claim 8-10 and 13, Struble '327 or Funke '897 and Altman '619 disclose the system and method substantially as claimed except for wherein the at least one drug improves myocyte calcium handling; increases the activity of sarcoplasmic reticulum Ca(2+) ATPase (SERCA2a) activity; and wherein

the drug is at least one of an adenovirus carrying a SERCA2a gene and an adeno associated virus carrying a phospholamban gene. However, Rosenzweig '010 (paragraphs [0016, 0018, 0119, 0157, 0165, 0207]) or the Miyamoto article (abstract) teach wherein the at least one drug improves myocyte calcium handling; increases the activity of sarcoplasmic reticulum Ca(2+).ATPase (SERCA2a) activity; and wherein the drug is at least one of an adenovirus carrying a SERCA2a gene and an adeno associated virus carrying a phospholamban gene.

One having ordinary skill in the art would appreciate that Struble '327 or Funke '897 and Altman '619 and Rosenzweig '010 or the Miyamoto article could be combined since they both teach the use of agents to treat heart disorders, and thus the references are analogous art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Struble '327 or Funke '897 and Altman '619 by incorporating the use of an gene therapy as taught by Rosenzweig '010 or the Miyamoto article in order to provide a more steady state approach for the delivery of therapeutic agents independent of the electrical activity of the heart (Altman '619: pg. 11, [0124]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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